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MAY 17 2005

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

Submitter's Name:	Theken Surgical
Address:	283 E. Waterloo Akron, Ohio 44319
Telephone Number:	330-773-7677 x221
Fax Number:	330-773-7697
Contact Person:	Randy Theken
Date Prepared:	5/16/2005 4:50 PM

B. Device Information

Trade Name:	Theken VU Vertebral Body Replacement (VBR) SYSTEM
Common Name:	Vertebral Body Replacement Device
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (per 21 CFR 888.3060)
Device Classification:	Class II (per 21 CFR 888.3060) Panel: Orthopedic, Product Code: MQP, Panel Code: 87
Predicate Device: Comparative Devices:	Theken Surgical LLC CPOD/LPOD VBR System (K032064) SIGNUS Medical LLC Tetris™ Spinal Implant (K022793) Synthes Spine Company, L.P. Synthes Synex™ Spacer System (K003836) Osteotech Inc., VBR™ (K003155) DePuy AcroMed, Inc. Stackable Cage™ System (K990148) SIGNUS Medical LLC Curved PEEK Tetris™ (K041888)
Material Composition:	Polyetheretherketone (PEEK OPTIMA LT) per ASTM F2026.
Subject Device Description:	The Theken VU VBR SYSTEM is comprised of rounded rectangular and rectangular cages with fenestrations and radii on all sides and toothed spikes which are used in combination with spacer components. The cages and spacer can be locked together into a variety of geometric configurations to fit each individual patient's pathology. The toothed spikes of the rounded rectangular and rectangular cages engage with the superior and inferior end plates of the neighboring vertebral bodies to resist rotation and migration. A single construct is sufficient to be used at all spinal levels and pathologies.
Intended Use:	The Theken VU VBR SYSTEM is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (e.g., fracture). The Theken VU VBR SYSTEM is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absences of fusion for a prolonged period. Bone graft material is recommended to be packed into the interior openings of the device prior to implantation. The Theken VU VBR SYSTEM is intended to be used with supplemental internal spinal fixation systems, such as the Theken BodyForm Thoracolumbar Fixation System(K983622, Approved 12/98) or the Theken Coral Pedicle Screw System (K041592, Approved 9/04).

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C. Substantial Equivalence

The technological characteristics of the Theken VU VBR SYSTEM are similar to the following predicate devices:

1) CPOD/LPOD VBR System (K032064), manufactured by Theken Surgical LLC and cleared by the FDA on February 20, 2004.
2) Tetris™ Spinal Implant (K022793), manufactured by SIGNUS Medical LLC and cleared by the FDA on April 8, 2003.
3) Synthes Synex™ Spacer System (K003836), manufactured by Synthes Spine Company, L.P. and cleared by the FDA on May 29, 2001.
4) VBR (K003155), manufactured by Osteotech Inc. and cleared by the FDA on October 16, 2001.
5) Stackable Cage™ System (K990148), manufactured by DePuy AcroMed, Inc. and cleared by the FDA on September 3, 1999.
6) Curved PEEK Tetris™ (K041888), manufactured by SIGNUS Medical LLC and cleared by the FDA on July 9, 2004.

Establishment of equivalence is based on similarities of intended use, design, and physical characteristics. All implants are used to treat the same conditions, have essentially the same precautions and contradictions for use, and have equivalent potential for complications for the risk of use. In addition they all represent a basic design concept in terms of safety and effectiveness, and differ only in minor details. Based on the design concept, the use of established well known materials, feature comparisons, mechanical testing, indications for use, pre-production quality assurance planning and engineering analysis (adherence to GLP), Theken Surgical believes that sufficient evidence exists to reasonably conclude that the VU VBR SYSTEM is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Mr. Randy Theken
Theken Surgical, LLC
283 E Waterloo Road
Akron, Ohio 44319

Re: K050058
Trade/Device Name: Theken VU VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: May 9, 2005
Received: May 12, 2005

Dear Mr. Theken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriamm Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050058

Device Name: Theken VU VBR SYSTEM

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050058